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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 09/670,537 | 09/27/2000 | Andrew P. Mazar | 38369-169219 | 6771 |
| 7590 | 05/28/2004 | | EXAMINER | |
| CATHRYN CAMPBELL CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE SAN DIEGO, CA 92122 | | | JONES, DAMERON LEVEST | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| Application No. | Applicant(s) | |
|-----------------|--------------|--|
| 09/670,537 | MAZAR ET AL. | |
| Examiner | Art Unit | |
| D. L. Jones | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 March 2004.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-49 is/are pending in the application.
4a) Of the above claim(s) 1-20, 24, 26, 28, 30, 32-34, 37, 40, 42, 44, 46 and 48 is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 21-23, 25, 27, 29, 31, 35, 36, 38, 39, 41, 43, 45, 47, and 49 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 3/3/04 wherein the specification and claims 22, 25, 35, and 36 were amended

Note: Claims 1-49 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 3/3/04 to the rejection of claims 21-23, 25, 27, 29, 31, 35, 38, 39, 41, 43, 45, 47, and 49 made by the Examiner under 35 USC 112 and/or 102 have been fully considered and deemed persuasive. Therefore, the said rejections are hereby withdrawn.

WITHDRAWN CLAIMS

3. Claims 1-20, 24, 26, 28, 30, 32-34, 37, 40, 42, 44, 46, and 48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejections

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 21-23, 25, 27, 29, 31, 35, 36, 38, 39, 41, 43, 45, 47, and 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling peptide compounds selected from (Chelator)-(Xaa)₂₋₆-(Lys,Arg)-(alkylating group)-uPA; (Label-Chelator)-(Xaa)₂₋₆-(Lys,Arg)-(alkylating group)-uPA; (Label)-(Xaa)₂₋₆-(Lys,Arg)-(alkylating group)-uPA; and (Therapeutic moiety)-(Xaa)₂₋₆-(Lys,Arg)-(alkylating group)-uPA, does not reasonably provide enablement for *all peptides* that bind to one or more sites of tcuPA or a fragment/subunit of tcuPA having a chelator, detectable label, or therapeutic moiety attached thereto. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to an uPA active site targeting peptide compound that binds to one or more sites of tcuPA or a fragment or subunit of tcuPA having attached thereto a detectable label, therapeutic moiety, of a chelator.

(2) State of the prior art

The references of record do not indicate which specific peptides or classes of peptides.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 21 encompasses a vast number of possible peptides. Applicant's specification does not enable the public to make or use such a vast number of peptides in combination with a detectable label, therapeutic moiety, or chelator.

(4) Level of predictability in the art

The art pertaining to the uPA site binding peptide compounds is highly unpredictable considering that the peptide is not set forth, but a general statement that the peptide binds a uPA active site. Determining the various types of peptides or classes of peptides that are uPA active peptide compounds requires various experimental procedures and without guidance that is applicable to all peptides, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claim 21 encompasses a vast number of peptides. Applicant's limited guidance does not enable the public to prepare such a numerous amount of peptides. There is no directional guidance for the specific peptides Applicant intends to

be encompassed by the instant invention that will bind to tcuPA or a fragment or subunit thereof would generate the desired results.

(6) Existence of working examples

Independent claim 21 encompasses a vast number of peptides. Applicant's limited working examples do not enable the public to prepare such a numerous amount of peptide compounds and combinations thereof. While Applicant's claims encompass a plethora of possible uPA peptide compounds, the specification discloses a limited number of peptide compounds, in combination with the detectable labels, therapeutic labels, and chelator.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible peptide compounds known to exist. In addition, the claims given their broadest interpretation also read on future uPA active site targeting peptides..

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 Second Paragraph Rejections

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 21-23, 25, 27, 29, 31, 35, 36, 38, 39, 41, 43, 45, 47, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on any possible peptide compound. However, one of ordinary skill in the art would not be able to ascertain what peptides Applicant are claiming that are compatible with the instant invention. Also, it is noted that in claim 22, for example, the variable 'Peptide Z' is defined as any peptide that binds to a surface exosite of uPA. Thus, the claims, as written, also encompass future peptides that may be found to bind the surface of uPA. Hence, Applicant is respectfully requested to clarify the claim in order that one may determine what is being claimed.

COMMENTS/NOTES

8. It should be noted that no prior art has been cited for the specific peptide compounds above for which Applicant is enabled. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipate nor renders obvious an uPA active site targeting peptide compound or uses thereof wherein

the peptide compounds have the formulae Chelator)-(Xaa)₂₋₆-(Lys,Arg)-(alkylating group)-uPA; (Label-Chelator)-(Xaa)₂₋₆-(Lys,Arg)-(alkylating group)-uPA; (Label)-(Xaa)₂₋₆-(Lys,Arg)-(alkylating group)-uPA; and (Therapeutic moiety)-(Xaa)₂₋₆-(Lys,Arg)-(alkylating group)-uPA.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D.L. Jones
Primary Examiner
Art Unit 1616